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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,937	10/07/2003	Thomas B. Stanford JR.	B-4588NP 620930-1	6021

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EXAMINER

MARTIN, PAUL C

ART UNIT	PAPER NUMBER
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1657

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/680,937	Applicant(s) STANFORD ET AL.	
	Examiner PAUL C. MARTIN	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 16, 17, 19-27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16, 17, 19-27 and 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 14, 16, 17, 19-27 and 29-33 are pending in this application and were examined on their merits.

The objection to Claims 20 and 21 for minor informalities has been withdrawn due to the Applicant's amendments to the Claims filed 10/15/08.

The rejection of Claims 14, 16, 17, 19-27 and 29-32 under 35 U.S.C. § 112, 1st paragraph, as failing to comply with the written description requirement has been withdrawn due to the Applicant's amendments to the Claims filed 10/15/08.

Claim Objections

Claim 14 is newly objected to because of the following informalities: Claim 14 states in the preamble that it is a method for determining an organism while in line 5 the method is newly drawn to identifying a presence of an organism. As one cannot determine an organism, "determining" should be replaced with "detecting" in view of the new amendments. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 14, 19, 20, 21, 22, 23, 24, 25, 26 and 29-32 are newly rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 28, 29, 37, 39, 43, 47, 48, 49 and 52 of U.S. Patent No. 7,008,524 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are drawn to similar methods wherein the variations are minor in nature and those of ordinary skill in the art would be able to envision the inventions as obvious variants. For example, the instant invention is drawn to a method of detecting an organism, using of a sensor comprising a substrate (glass, ceramic, plastic), more than one pair of interdigitated electrodes (gold, platinum, silver, copper, combinations thereof), a sol-gel matrix encapsulating more than one enzyme, and an inherently conductive polymer transducer material such as an organosilane wherein the organism expresses a organism enzyme that reacts with a reactant in the sensor producing products that further react with the sol-gel enzyme to produce products which modulate electrical resistance of the transducer which is measured by the electrodes. Patent '524 is drawn to a method of detecting a chemical or biological molecule or a pathogen (biological molecules and pathogens can be organisms), using of a sensor comprising a dielectric substrate (quartz, glass, ceramic, plastic), more than one pair of interdigitated electrodes (gold), a sol-gel matrix encapsulating more than one enzyme (ensconced within), and an inherently conductive polymer transducer material such as an organosilane.

While the '524 Patent does not indicate the process by which the pathogen or biological molecule produces that change in current flow one of ordinary skill in the art being familiar with enzyme biosensors could envision a linked reaction process by which the reactants of some

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substance produced by the pathogen react with enzymes within the sol-gel to modulate the electrical resistance. As there are only finite ways that an enzyme sol-gel biosensor can operate those of ordinary skill in the art would have recognized the methodology presented by the instant application when in possession of the '524 Patent.

Claims 14, 19, 20, 21, 22, 23, 24, 25, 26 and 29-32 are newly rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 28, 29, 37, 39, 43, 47, 48, 49 and 52 of U.S. Patent No. 6,730,212 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are drawn to similar methods wherein the variations are minor in nature and those of ordinary skill in the art would be able to envision the inventions as obvious variants.

For example, the instant invention is drawn to a method of detecting an organism, using of a sensor comprising a substrate (glass, ceramic, plastic), more than one pair of interdigitated electrodes (gold, platinum, silver, copper, combinations thereof), a sol-gel matrix encapsulating more than one enzyme, and an inherently conductive polymer transducer material such as an organosilane wherein the organism expresses a organism enzyme that reacts with a reactant in the sensor producing products that further react with the sol-gel enzyme to produce products

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which modulate electrical resistance of the transducer which is measured by the electrodes.

Patent '212 is drawn to a method for detecting a biological material in the air (such as an airborne microorganism), using of a sensor comprising a dielectric substrate (glass, ceramic, plastic), more than one pair of interdigitated electrodes (gold), a sol-gel matrix encapsulating more than one enzyme (bioindicator molecules) (ensconced within), and an inherently conductive polymer transducer material such as an organosilane. While the '121 Patent does not indicate the process by which the biological material produces that change in current flow one of ordinary skill in the art being familiar with enzyme biosensors could envision a linked reaction process by which the reactants of some substance produced by the pathogen react with enzymes within the sol-gel to modulate the electrical resistance. As there are only finite ways that an enzyme sol-gel biosensor can operate those of ordinary skill in the art would have recognized the methodology presented by the instant application when in possession of the '524 Patent.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 16, 17, 19-27 and 29-32 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Amended Claim 14 is drawn to a sensor

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comprising at least one reactant and more than one sol-gel enzyme. As the Applicant's invention differs from the Prior Art in that the sol-gel enzymes are different types, it is unclear how multiple enzyme species will all react with at least one reactant as enzymes have different substrates and specificities. The presence of more than one reactant would be necessary for multiple enzymes to be able to generate signals. For example, Claim 27 requires that the at least one reactant is a starch containing amylase. It is unclear what other enzymes besides amylase would react with the substrate. Claims 16, 17, 19-27 and 29-32 are rejected as being dependent upon rejected Claim 14.

Claims 14, 16, 17, 19-27 and 29-32 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended Claim 14 requires that the modulated electrical resistance of the transducer material be measured. It is unclear by what means the electrical resistance will be measured.

Claim 25 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 lists sol-gel enzymes for use in the invention of Claim 14. Claim 14 requires that the products produced by the reaction of the sol-gel enzyme with the reaction products of the organism-enzyme and reactant be able to modify an electrical resistance. It is unclear how enzymes with no oxidoreductase activity, such as gelatinase, β -lactamase, casease, citrase, deoxyribonuclease, lipase, β -galactosidase, phenylalanine deaminase, 1-

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pyrrolidonyl arylamidase, cysteine desulfurase, urease, L-asparaginase, organophosphorus hydrolase, acetylcholinesterase or α -amylase will function in the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33 is newly rejected under 35 U.S.C. § 103(a) as being unpatentable over Keyes (US 4,169,765) in view of Yamagishi *et al.* (US 6,730,212 B1).

Keyes teaches method for the detection of α -amylase produced by an organism, using a sensor comprising a substrate-surface immobilized amylose starch reagent is contacted with a sample containing α -amylase expressed by an organism, the α -amylase catalyzes the reaction of starch to form oligosaccharides which react with immobilized glucoamylase to form glucose, glucose oxidation is catalyzed by immobilized glucose oxidase to form the different products gluconic acid and H_2O_2 , wherein the amount glucose is measured indirectly by detecting the amount of current generated by the H_2O_2 with an electrode (Column 4, Lines 1-20 and Column 30, Claims 1-3).

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Keyes does not teach a method wherein the different products modulate electrical resistance of a transducer.

Yamagishi *et al.* teaches a sensor comprising a glass substrate on which interdigitated, polyaniline comprising electrodes are deposited, covered by a sol-gel matrix containing the inherently conductive, water-soluble polyaniline polymer tetramethoxy orthosilicate (TMOS) and encapsulating an enzyme (glucose oxidase), wherein glucose oxidation is catalyzed by the glucose oxidase to form gluconic acid and H_2O_2 modulating the electrical resistance of the conductive polymer detected by applying voltage and registering the change in current with an amperometer (Column 3, Lines 30-61 and Columns 15 and 16, Claims 1-3 and Column 17, Claims 9-12 and 14).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the enzyme immobilized sensor method for the detection of (α -amylase produced by an organism as taught by Keyes above with the enzyme-encapsulated, conductive polymer sol-gel biosensor as taught by Yamagishi *et al.* above because both methods are drawn to the use of immobilized enzymatic

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biosensors in the detection and measurement of an environmental enzyme of interest. One of ordinary skill in the art would have recognized that the use of an ohmmeter to measure the electrical resistance instead of the ammeter used to measure current as taught by Yamagishi *et al.* would have been a matter of artisan preference as both methods are used to determine electrical current. In particular, the method of Yamagishi *et al.* is advantageous over the solitary method of Keyes, which relies on laboratory specific analytical techniques such as polarography, mass spectroscopy and "wet" chemistry.

There would have been a reasonable expectation of success in making this combination because both methods rely upon substrate immobilized enzyme technology, particularly the use of glucose oxidase in the oxidation of glucose to form gluconic acid and hydrogen peroxide and the measurement of the electrical current derived from this reaction.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348.

The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

01/02/09

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657